Docket No.: 85849DIV4(308597)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Andrew Segal et al.

Application No.: 10/666,833 Confirmation No.: 6845

Filed: September 19, 2003 Art Unit: 1648

For: LECTIN COMPOSITIONS AND METHODS FOR MODULATING AN IMMUNE RESPONSE TO AN ANTIGEN Examiner: B. Blumenthal

RESPONSE TO FINAL OFFICE ACTION AND REQUEST FOR CONTINUED EXAMINATION

MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Office Action dated August 31, 2011, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) A composition suitable for administration to a subject, said composition comprising an antigen bearing target and an isolated fusion polypeptide, said fusion polypeptide comprising

a first amino acid sequence which can bind to a carbohydrate

and

a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte,

wherein said composition includes said fusion polypeptide bound to a carbohydrate on said antigen bearing target, wherein said fusion polypeptide is incubated with said antigen bearing target to achieve binding, and includes said fusion polypeptide which is not bound to said antigen bearing target.

2. (Previously presented) The composition of claim 1, wherein said ligand is chosen from the group: a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for a heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule, a ligand for an opsonin receptor.

3. (Previously presented) The composition of claim 2 wherein said ligand comprises at least five contiguous amino acids of a naturally occurring cytokine, said cytokine being chosen from the group: GM-CSF, an interleukin, a chemokine, an interferon, a TNF-alpha, a flt-3 ligand.

4. (Withdrawn) The vaccine composition of claim 2 wherein said ligand comprises at least about five contiguous amino acids of a naturally occurring CD154 molecule.

5. (Previously presented) The composition of claim 1, wherein said antigen bearing target is chosen from the group: a tumor cell, a virus, a bacterial cell, a fungal cell, a cell of a parasite, a prion, a mammalian cell, an insect cell, and a polypeptide free of other cell-derived material.

6. (Previously presented) The composition of claim 5, wherein said antigen bearing target is pathogenic.

7. (Previously presented) The composition of claim 5, wherein said antigen bearing target is attenuated.

8. (Currently amended) The composition of claim 1, wherein said antigen bearing target is a cell which divides at a rate that is less than about 50% of the rate of division of corresponding cells which are not treated to ~~prevent~~ inhibit cell division.

9. (Previously presented) The composition of claim 1, wherein said leukocyte is an antigen presenting cell.

10. (Previously presented) The composition of claim 9, wherein said leukocyte is a professional antigen presenting cell.

11. (Previously presented) The composition of claim 9, wherein said leukocyte is a dendritic cell.

12. (Previously presented) The composition of claim 1, wherein said first amino acid sequence can bind to a sialic acid on a glycoprotein.

13. (Previously presented) The composition of claim 1, wherein said first amino acid sequence comprises a carbohydrate-binding domain of a naturally occurring lectin.

14. (Currently amended) The composition of claim 8, wherein said cell divides at a rate that is less than about 30-50% of the rate of division of corresponding cells which are not treated to ~~prevent~~ inhibit cell division.

REMARKS

Claims 1-14 are pending. Claim 4 is withdrawn. Claims 1, 8, and 14 are amended. Accordingly, upon entry of the amendment, claims 1-14 will be pending.

The claims have been amended to claim more fully the recited subject matter and to make minor editorial changes. Support for the amendments can be found throughout the claims and specification as filed, and is discussed in more detail below. Specifically, support for the amendment may at least be found in the originally filed specification, for example, at page 24, lines 8-15. Support for the amendment of claims 8 and 14 may at least be found in the originally filed specification, for example, at the paragraph bridging page 161 and 162. No new matter is added.

Amendment of the claims herein is not to be construed as acquiescence to any objections/rejections set forth in the instant Office Action and were done solely to expedite prosecution of the application. Applicants reserve the right to pursue the subject matter of the claims as originally filed in this or one or more subsequent patent applications.

Interview Summary

At the outset, Applicants would like to thank Examiner Blumenthal for taking the time to discuss the outstanding rejections with Applicants' representatives on November 15, 2011 (the "Interview"). Applicants' representatives thank Examiner Blumenthal for providing comments regarding the prosecution of this application and for responding to the Office Action. Applicant's representative submits herewith an amendment and response, incorporating the Examiners' suggestions, as discussed in the Interview.

Obviousness-type Double Patenting

The Office Action states that the instant claims are rejected under the judicially created doctrine of obviousness type double patenting in view of several co-pending

applications. Upon notification of otherwise allowable subject matter in the instant case, Applicants will address the double patenting rejections.

Claim Rejections – 35 U.S.C. §112

Claim 8 is rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. The Office Action at page 4 alleges that claim 8 is unclear for reciting "wherein said cell divides at a rate that is less than about 50% of the rate of division of corresponding cells which are not treated to prevent cell division." Applicants respectfully disagree and traverse the rejection.

Without acquiescing to the reasoning underlying the rejection and in order to expedite prosecution, Applicants have amended claims 8 and 14 to recite "wherein said cell divides at a rate that is less than about 50% of the rate of division of corresponding cells which are not treated to inhibit cell division." Applicants respectfully submit that the metes and bounds of claims 8 and 14 are clear. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejections – 35 U.S.C. §102

Claims 1-3 and 5-7, and 9-13 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by U.S. 5,891,432 to Hoo et al. ("Hoo") as evidenced by U.S. Patent Publication 2003/0206917 to Varki and Zheng ("Varki"). Applicants respectfully disagree and traverse the rejection.

Without acquiescing to the reasoning underlying the rejection and solely to expedite prosecution, claim 1 has been amended to recite that the fusion polypeptide is "an isolated fusion polypeptide" and that "said fusion polypeptide is incubated with said antigen bearing target to achieve binding." Thus, the presently claimed invention is a composition suitable for administration to a subject, said composition comprising an antigen bearing target and an isolated fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence which can bind to a carbohydrate and a second

amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein said composition includes said fusion polypeptide bound to a carbohydrate on said antigen bearing target, wherein said fusion polypeptide is incubated with said antigen bearing target to achieve binding, and includes said fusion polypeptide which is not bound to said antigen bearing target.

For a reference to serve as the basis for an anticipation rejection that reference must disclose each and every element present in the claim (M.P.E.P. §2131). In contrast, Hoo fails to teach or suggest an isolated fusion protein that is incubated with said antigen bearing target to achieve binding, as presently recited. Instead, Hoo teaches a cell expressing a fusion protein that is inserted into the plasma membrane by a variety of transmembrane domains (col. 7, ln. 21 – col. 8, ln. 14). Thus, Hoo does not teach isolating the fusion protein or binding the isolated fusion protein to an antigen bearing target (e.g., a cell) by incubating the isolated fusion protein with the antigen bearing target. Moreover, Hoo does not teach or suggest a composition containing a fusion polypeptide bound to a carbohydrate on an antigen bearing target by a cell-surface binding moiety, as presently claimed.

In support of the rejection, the Examiner has further cited Varki as an evidentiary reference. However, Varki does not remedy the deficiencies of Hoo. Varki is a review article that teaches interactions among blood cells mediated by selectins (Abstract). Like Hoo, Varki fails to teach isolating a fusion protein comprising a selectin, or binding an isolated fusion protein comprising a selectin to a cell by incubating the isolated fusion protein with a cell, as presently claimed. Thus, Varki does not make up for the deficiencies of Hoo in this regard.

In sum, Hoo does not teach isolating a fusion protein comprising an amino acid sequence which can bind a carbohydrate or binding such an isolated fusion protein to an antigen bearing target (e.g., a cell) by incubating the isolated fusion protein with the antigen-bearing target, as recited in the instant claims. Even as evidenced by Varki, Hoo does not teach each and every element of the presently claimed invention.

Therefore, Hoo, either alone or in combination with Varki, does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

In view of the foregoing amendments and arguments, Applicants respectfully request reconsideration and withdrawal of all pending objections/rejections and allowance of the applications with claims 1-3 and 5-14 presented herein. If a telephone call with Applicants' representative would be helpful in expediting prosecution of the application, Applicants invite the Examiner to contact the undersigned at the telephone number shown below.

Applicants submit this paper in response to the office action dated August 31, 2011, along with a Request for Continued Examination, and a Petition for One-month Extension of Time. Applicants hereby authorize the Director to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to Deposit Account No. **04-1105**, under Order No. 85849DIV4(211111).

Dated: January 3, 2012

Respectfully submitted,

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